

Claims

1. A vaccine for the treatment or prophylaxis of *C. difficile* associated disease, the vaccine comprising a *C. difficile* gene or a *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof which is immunogenic in humans.
2. A vaccine for the treatment or prophylaxis of *C. difficile* associated disease, the vaccine comprising a *C. difficile* gene or *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof to which immunoreactivity is detected in individuals who have recovered from *C. difficile* infection.
3. A vaccine as claimed in claim 1 or 2 wherein the gene encodes a *C. difficile* surface layer protein, SlpA or variant or homologue thereof.
4. A vaccine as claimed in claim 1 or 2 wherein the peptide/polypeptide is a *C. difficile* surface layer protein, SlpA or variant or homologue thereof.
5. A vaccine as claimed in any of claims 1 to 4 wherein the vaccine comprises a chimeric nucleic acid sequence.
6. A vaccine as claimed in 5 wherein the chimeric nucleic acid sequence is derived from the 5' end of the gene, encoding the mature N-terminal moiety of SlpA from *C. difficile*.
7. A vaccine as claimed in any of claims 1 to 4 wherein the vaccine comprises a chimeric peptide/polypeptide.

8. A vaccine as claimed in 7 wherein the amino acid sequence of the chimeric peptide/polypeptide is derived from the mature N-terminal moiety of SlpA from *C. difficile*.
- 5 9. A vaccine as claimed in any of claims 1 to 8 wherein the vaccine contains an amino acid sequence SEQ ID No.1 or a derivative or fragment or mutant or variant thereof.
- 10 10. A vaccine as claimed in any of claims 1 to 8 wherein the vaccine contains an amino acid sequence SEQ ID No.2 or a derivative or fragment or mutant or variant thereof.
- 15 11. A vaccine as claimed in any of claims 1 to 8 wherein the vaccine contains a nucleotide sequence SEQ ID No.3 or a derivative or fragment or mutant or variant thereof.
12. A vaccine as claimed in any of claims 1 to 8 wherein the vaccine contains a nucleotide sequence SEQ ID No.4 or a derivative or fragment or mutant or variant thereof.
- 20 13. A vaccine as claimed in any of claims 1 to 8 wherein the vaccine contains a nucleotide sequence SEQ ID No.5 or a derivative or fragment or mutant or variant thereof.
- 25 14. A vaccine as claimed in any of claims 1 to 8 wherein the vaccine contains a nucleotide sequence SEQ ID No.6 or a derivative or fragment or mutant or variant thereof.
- 30 15. A vaccine as claimed in any of claims 1 to 8 wherein the vaccine contains a nucleotide sequence SEQ ID No.7 or a derivative or fragment or mutant or variant thereof.

16. A vaccine as claimed in any of claims 1 to 8 wherein the vaccine contains a nucleotide sequence SEQ ID No.8 or a derivative or fragment or mutant or variant thereof.
17. A vaccine as claimed in any of claims 1 to 8 wherein the vaccine contains a nucleotide sequence SEQ ID No.9 or a derivative or fragment or mutant or variant thereof.
18. A vaccine as claimed in any of claims 1 to 8 wherein the vaccine contains a nucleotide sequence SEQ ID No.10 or a derivative or fragment or mutant or variant thereof.
19. A vaccine as claimed in any preceding claim in combination with at least one other *C. difficile* sub-unit.
20. A vaccine for the treatment or prophylaxis of *C. difficile* associated disease, the vaccine comprising the mature N-terminal moiety of a surface layer protein, SlpA of *C. difficile* or variant or homologue thereof which is immunogenic in humans.
21. A vaccine as claimed in claim 20 wherein the N-terminal moiety of SlpA contains an amino acid sequence SEQ ID No. 1.
22. A vaccine as claimed in claim 20 wherein the N-terminal moiety of SlpA contains an amino acid sequence SEQ ID No. 2.
23. A vaccine for the treatment or prophylaxis of *C. difficile* associated disease, the vaccine comprising an immunodominant epitope derived from a *C. difficile* gene or a *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof which is immunogenic in humans.

24. A vaccine as claimed in any preceding claim comprising a pharmaceutically acceptable carrier.
25. A vaccine as claimed in any preceding claim in combination with a pharmacologically suitable adjuvant.
26. A vaccine as claimed in claim 25 wherein the adjuvant is interleukin 12.
27. A vaccine as claimed in claim 25 or 26 wherein the adjuvant is a heat shock protein.
28. A vaccine as claimed in any preceding claim comprising at least one other pharmaceutical product.
29. A vaccine as claimed in claim 28 wherein the pharmaceutical product is an antibiotic.
30. A vaccine as claimed in claim 29 wherein the antibiotic is selected from one or more metronidazole, amoxycillin, tetracycline or erythromycin, clarithromycin or tinidazole.
31. A vaccine as claimed in claim 28 wherein the pharmaceutical product comprises an acid-suppressing agent such as omeprazole or bismuth salts.
32. A vaccine as claimed in any preceding claim in a form for oral administration.
33. A vaccine as claimed in any preceding claim in a form for intranasal administration.
34. A vaccine as claimed in any preceding claim in a form for intravenous administration.
35. A vaccine as claimed in any preceding claim in a form for intramuscular administration.

36. A vaccine as claimed in any of claims 1 to 35 including a peptide delivery system.
- 5 37. An immunodominant epitope derived from a *C. difficile* gene or a *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof.
38. An immunodominant epitope as claimed in claim 37 wherein the *C. difficile* peptide/polypeptide contains an amino acid sequence SEQ ID No.1 or SEQ ID No.2 or a derivative or fragment or mutant or variant thereof.
- 10 39. An immunodominant epitope as claimed in claim 35 wherein the *C. difficile* peptide/polypeptide contains an amino acid sequence SEQ ID No.3 or SEQ ID No.4 or SEQ ID No.5 or SEQ ID No.6 or SEQ ID No.7 or SEQ ID No.8 or SEQ ID No. 9 or SEQ ID No. 10 or a derivative or fragment or mutant or variant thereof.
- 15 40. A chimeric nucleic acid sequence derived from the 5' end of the slpA gene encoding the mature N-terminal moiety of SlpA from *C. difficile* which is immunogenic in humans.
- 20 41. A chimeric peptide/polypeptide wherein the amino acid sequence of the chimeric peptide/polypeptide is derived from the mature N-terminal moiety of SlpA from *C. difficile*.
- 25 42. A *C. difficile* peptide comprising SEQ ID No. 1.
43. A *C. difficile* peptide comprising SEQ ID No. 2.
- 30 44. A *C. difficile* gene comprising SEQ ID No. 3.

45. A *C. difficile* gene comprising SEQ ID No. 4.

46. A *C. difficile* gene comprising SEQ ID No. 5.

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48. A *C. difficile* gene comprising SEQ ID No. 7.

49. A *C. difficile* gene comprising SEQ ID No. 8.

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50. A *C. difficile* gene comprising SEQ ID No. 9.

51. A *C. difficile* gene comprising SEQ ID No. 10.

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52. The use of a *C. difficile* gene or a *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof which is immunogenic in humans in the preparation of a medicament for use in a method for the treatment or prophylaxis of *C. difficile* infection or *C. difficile* associated disease in a host.

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53. The use as claimed in claim 52 wherein the medicament which is prepared is a vaccine ~~(as claimed in any of claims 1 to 36.)~~

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54. A method for preparing a vaccine for prophylaxis or treatment of *C. difficile* associated disease, the method comprising;

obtaining a *C. difficile* gene or a *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof which is immunogenic in humans; and

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forming a vaccine preparation comprised of said gene or peptide/polypeptide or derivative or fragment or mutant or variant, which is suitable for administration to a host and which when administered raises an immune response.

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55. A method as claimed in claim 54 wherein the *C. difficile* peptide/polypeptide contains an amino acid sequence SEQ ID No.1 or SEQ ID No.2 or a derivative or fragment or mutant or variant thereof.

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56. A method as claimed in claim 54 wherein the *C. difficile* gene contains an amino acid sequence SEQ ID No.3 or SEQ ID No.4 or SEQ ID No.5 or SEQ ID No.6 or SEQ ID No.7 or SEQ ID No.8 or SEQ ID No.9 or SEQ ID No.10 or a derivative or fragment or mutant or variant thereof.

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57. A method for prophylaxis or treatment of *C. difficile* associated disease, the method comprising;

obtaining a *C. difficile* gene or a *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof which is immunogenic in humans;

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forming a vaccine preparation comprised of said gene or peptide/polypeptide or derivative or fragment or mutant or variant, and

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administering the vaccine preparation to a host to raise an immune response.

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58. Monoclonal or polyclonal antibodies or fragments thereof, to a *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof which is immunogenic in humans.

59. Monoclonal or polyclonal antibodies or fragments thereof, to *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof to which immunoreactivity is detected in individuals who have recovered from *C. difficile* infection.

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60. Purified antibodies or serum obtained by immunisation of an animal with a vaccine according to any of claims 1 to 36.

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61. The use of the antibodies or fragments as claimed in claims 58 and 59 in the preparation of a medicament for treatment or prophylaxis of *C. difficile* infection or *C. difficile* associated disease.

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62. The use of the antibodies or serum as claimed in 60 in the preparation of a medicament for treatment or prophylaxis of *C. difficile* infection or *C. difficile* associated disease.

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63. The use of the antibodies or fragments or serum as claimed in any of claims 58 to 60 for use in passive immunotherapy for established *C. difficile* infection.

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64. The use of the antibodies or fragment or serum as claimed in any of claims 58 to 60 for the eradication of *C. difficile* associated disease.

65. Use of interleukin 12 as an adjuvant in *C. difficile* vaccine.

66. The use of humanised antibodies or serum for passive vaccination of an individual with *C. difficile* infection.